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Building an Institutional Clinical Research Professionals Group at an Academic Institution: Evidence of Need and Initial Structure

Demi Beckford, MHS; Kelly Boone, MA, CCRP; Jessica Fritter, MACPR, ACRP-CP; Grace Wentzel, CCRP, CHRC

Nationwide Children's Hospital has an expansive clinical research portfolio that has continued to increase in number and complexity over the last five to seven years. As this has occurred, the number of clinical research staff being hired across the organization has steadily increased to approximately 2,100 in the last five years. With such a large group of clinical research professionals, a program to serve as a central point for staff to connect and obtain resources became essential. This led to the creation of Bloom: Clinical Research Professionals Group (Bloom).

Bloom is one of two initiatives under the hospital's Research Matters committee, which is managed in the Abigail Wexner Research Institute and is overseen by the Director of Safety and Training. The mission of Research Matters is to serve as a resource to the hospital and research institute community, including patients and families, on issues related to both basic science and clinical research activities.

The other initiative under Research Matters is the Research Institute Diversity Enrichment (RIDE), with a mission to engage the research community through education, celebration, and promotion of diversity. Bloom and RIDE work in tandem across the organization.

Bloom was established in 2020 with the purpose of building a network of clinical research professionals and providing a space to collaborate, receive education and training, and find mentors/mentees within a large pediatric academic medical institution that integrates both a free-standing pediatric hospital and a dedicated research institute. Bloom is overseen by the Director of Clinical Research Services. Bloom does not have an operating budget; however, there are some internal funds that Bloom can utilize.

Bloom leadership consists of research-affiliated departments across the hospital, including Hematology/Oncology/Blood and Marrow Transplant, Clinical Research Services, and the Behavioral Trials Office. There are three main positions within the Bloom steering committee: Program Chair, Education and Activities Coordinator, and Administrative Coordinator. The steering committee has a rolling membership of two years for leadership roles within the program.

The leadership aims to strengthen and enhance the clinical research community by connecting its professionals and providing them with resources and opportunities to discuss timely topics, address knowledge gaps, and expand the community. The goal of Bloom is to create a sense of belonging within the organization and foster retention. Currently, there are very few instances in the literature discussing how and why to build and maintain a group for institutional research professionals like Bloom.

Our objective in this article is to describe the baseline characteristics and needs of members as well as the structure of Bloom. We discuss the benefits of the group and conclude with how an institutional group for clinical research professionals can develop, enhance, and strengthen an institution's clinical research community.

Methods

In collaboration with our project managers, the authors designed two surveys (a baseline/interest survey and the first annual member survey for the conclusion of Bloom's first year of activity) to distribute among clinical research employees.

The baseline survey included 12 items and was distributed through multiple channels, such as employee engagement e-mail lists and employee news e-mail lists. The baseline survey asked for employment (e.g., years in clinical research, job title) and demographic (e.g., education level, clinical research certification) information. It also asked what educational topics, speakers, and/or service opportunities members would like to see facilitated through Bloom.

In addition to gathering baseline data, the survey obtained e-mails, and thus prompted an e-mail list that enabled efficient and timely distribution of information on Bloom events and research-related policies (e.g., COVID updates). Summary statistics describing employment and demographic characteristics and broad themes were identified to summarize engagement opportunities of interest to members (see Appendix A).

Those who completed the baseline survey and became members of Bloom were then given a 16-item survey which was distributed via e-mail one year after the inception of the group (see Appendix B). This consisted of questions regarding professional certification and job promotion status within the previous year. There was a section for open comments to facilitate suggestions for group resources and networking opportunities.

The survey tool used was Research Electronic Data Capture (REDCap) software. Under 45 CFR 46.101 in the *Code of Federal Regulations,* the Nationwide Children's Hospital Institutional Review Board was able to exempt the survey tool. The survey was live for five weeks and results were downloaded from REDCap for analyses. Data were analyzed using summary statistics.

The first annual member survey was distributed to clinical research staff who were members of Bloom during the winter of 2021. Group members consist of research professionals from three categories: Abigail Wexner Research Institute at Nationwide Children's Hospital, other areas of Nationwide Children's Hospital, and The Ohio State University Medical Center. The questions focused on demographics, site-specific training, job titles, research professional certification, promotions, content of meetings, skill level, and open comments/suggestions. Using a five-point Likert scale, participants were asked to rate the competencies obtained during Bloom sessions from "strongly disagree" to "strongly agree" (see Figure 1).

**Figure 1: Likert Scale One-Year Survey Responses**
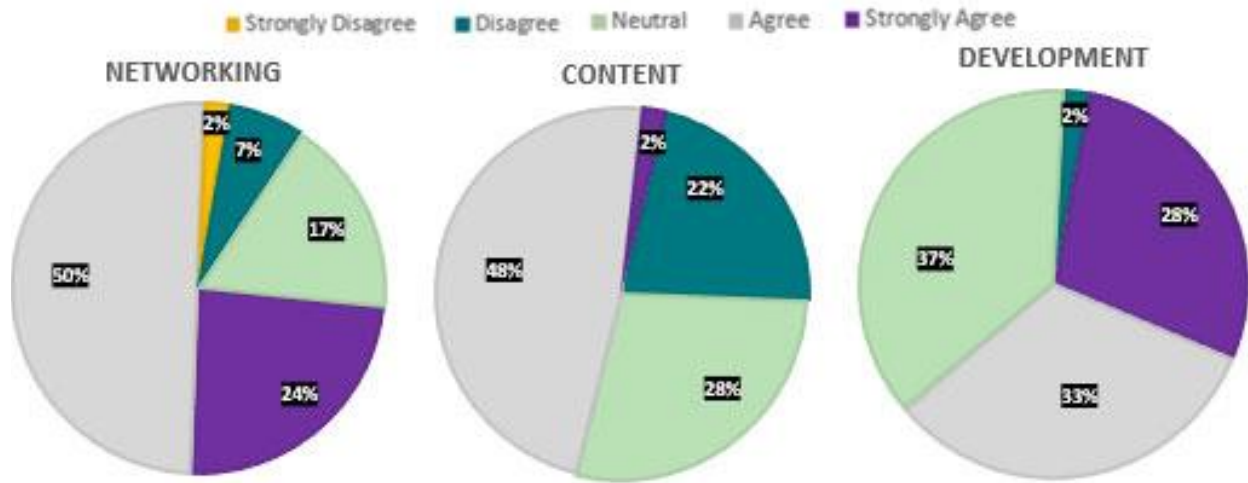
Results

The baseline/interest survey had 172 respondents across a variety of clinical research roles: 72% Clinical Research Coordinators (CRCs), 9% Research Managers, 8% Investigators, 3% Research Assistants, 5% Research Administration, and 3% Data Analysts/Managers (see Figure 2). The median length of time engaged in clinical research was three years (with a maximum of 37 years), with 26% of respondents starting employment at the institution within the past year. More than half (52%) of respondents were research institute (vs. hospital) employees. Five percent had an associate degree or lower, 56% had a bachelor's degree, 22% had a master's degree, and 17% had an MD or PhD. At baseline, only 17% of respondents had a clinical research certification, but 83% of those who did not have this credential were interested in pursuing a certification.

Figure 2: Group Membership Role Breakdown

Broad themes that emerged in terms of what members would like to gain from involvement in the group include topics related to clinical research operations (33%); professional development and education (26%); professional networking opportunities (23%); study design, writing, and analysis (17%); and clinical research certification and maintenance (15%) (see Figure 3). Topics of interest were not associated with years in clinical research.

Figure 3: Broad Theme Topics
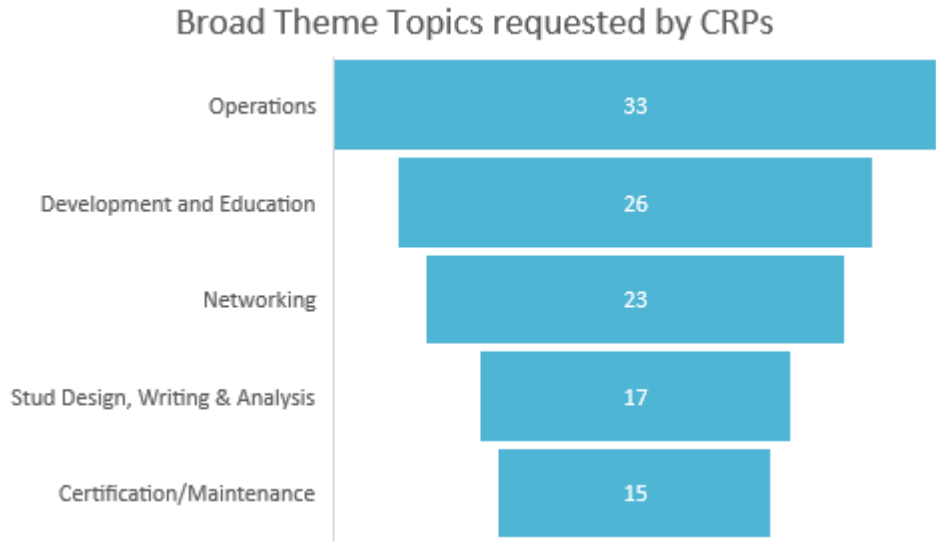
For the first annual member survey, 47 of 172 recipients responded (27%). Within one year from the creation of the program, Bloom supported fees associated with obtaining a clinical research certification for five members. Two members were promoted (Research Regulatory Coordinator to Research Regulatory Specialist; CRC I to CRC II). Almost three-quarters (74%) of respondents indicated that Bloom provided networking opportunities and 70% thought that the content of the meetings/seminars were useful. Sixty-one percent indicated that the group enhanced their professional development.

Discussion

At its conception, Bloom was structured to host a monthly meeting with themes relating to researcher spotlights, educational topics (continuing education credits provided), and networking and service opportunities. Sub-groups were also created called People Like Me groups, which

consisted of research professionals with similar titles and responsibilities. The purpose of these groups was to engage, support, and provide resources to members by holding quarterly meetings to enable networking within the organization.

Bloom meetings began in May of 2020 during the early days of the COVID-19 pandemic. This affected the structure of the group and its ability to host in-person networking functions. All in-person meetings and events were reformatted to virtual, with the highest attendance rate being 74% and an average attendance rate of 52%. As a result of no in-person meetings or events, we measured the group's effectiveness by relying heavily on virtual meeting interactions and survey responses.

We used feedback received in the first annual member survey to determine the 2022 schedule. This includes more in-person networking opportunities (as COVID-19 allows), a clinical research speaker series, and more in-depth discussions surrounding grant management, diversity/inclusion trainings, and other appropriate topics. A monthly newsletter will also be implemented to further integrate different areas of research. This newsletter will include current research job openings, relevant research trainings and seminars from other organizations, as well as departmental spotlights to increase collaboration.

Initiatives offered through this group benefit the clinical research community by facilitating interdisciplinary collaboration, with the aims of achieving optimal results and increasing organizational efficiency and compliance.

Limitations

One limitation to this study is that the outcomes rely on self-report. In addition, although this survey captured respondents from three different categories of employment, our results may not be generalizable because only 27% of members responded. Another limitation is due to the COVID-19 pandemic guidelines; these guidelines prohibited the group from conducting some 2020 and 2021 agenda items that were set prior to COVID-19. These events included meeting in person to provide further networking/hands-on learning opportunities, which may have affected the survey responses.

Conclusion

Clinical research professionals at a large pediatric academic medical center are eager to find a space to connect with their colleagues across the institution, regardless of years in the profession. To fill this gap, we created a group that offers regular steering committee meetings, speaking engagements, and educational sessions, it also provides various networking opportunities and financial and educational support to obtain/maintain a clinical research certification. Collectively, initiatives offered through this group benefit the clinical research community by facilitating cross-cutting collaboration, with the aims of achieving optimal results and increasing organizational efficiency and compliance. This group will continue to develop by enlisting new members and conducting routine follow-up surveys to gauge the relevance of provided sessions, as well as to identify needs of members.

Acknowledgement

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Editor's Note: In between the acceptance of this article for publication and its appearance online, Bloom was rebranded as Children's Hospital Clinical Research Professionals (CHIRP).

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Demi Beckford, MHS, (demi.beckford@nationwidechildrens.org) is a Planning and Business Development Project Manager for CONNECT – NeuroOncology Clinical Trials at Nationwide Children's Hospital in Columbus, Ohio.

Kelly Boone, MA, CCRP, is Associate Director of the Behavioral Trials Office in the Center for Biobehavioral Health at the Abigail Wexner Research Institute, Nationwide Children's Hospital.

Jessica Fritter, MACPR, ACRP-CP, is Clinical Research Administration Manager with the Department of Clinical Research Services at Nationwide Children's Hospital.

Grace Wentzel, CCRP, CHRC, is Director of Clinical Research Services with Nationwide Children's Hospital.

Strategies for Selecting Appropriate Satellite Sites for Clinical Research

Esther Mahillo, PhD, MBA

Today, there are more than 15,000 open or planned clinical trials in the United States, approximately 5,500 of which are for oncology therapies. With large cancer centers like MD Anderson and Memorial Sloan Kettering managing an estimated 1,100 and 700 clinical trials, respectively—and with the number of studies expected to expand at a compound annual growth rate of 5.7% from 2021 to 2028—there exists a tremendous opportunity for satellite sites to support the expansion of this $44 billion dollar industry.{1}

Investigator satellite sites are an important and underutilized strategic resource, and some in the industry even see them as the [next rising star in clinical research](#). The term "satellite site," as it relates to clinical trials, has been used in various contexts throughout the years. For the purposes of this article, the term covers independently operated study sites based within private physician practices, standalone hospitals, and other small, typically community-based, sites which large academic medical centers (AMCs) can turn to for help with certain trials on a case-by-case basis. It does not include sites that are run directly by sponsor organizations or as members of site management organizations, research consortia, or other forms of large research networks.

Due to historic misconceptions about their capabilities, resources, and output, satellite sites are often overlooked in clinical research. Today, however, these sites may be fully equipped with modern infrastructures and feature practitioners trained at prominent cancer centers of excellence who have vast clinical trial experience. The potential of these sites to add value in oncology clinical trials, as discussed further below, is tremendous, in that they often feature well-trained staff who can be dedicated to research projects, have experience with lab sampling, and understand the complexities of handling investigational products (IPs).

When added on an as-needed (temporary) basis to an existing AMC network of sites to contribute to the conduct of complex, multisite trials, satellite sites often already have all the necessary equipment to run such studies, and can quickly come up to speed with the robust compliance protocols and established standard operating procedures (SOPs) necessary for IP transfers from the primary site to the satellite. Some AMCs even make it easier for satellite sites to participate by using centralized institutional review board (IRB) approvals and employing uniform methods for capturing electronic delegation of authority logs. The symbiotic relationship between satellites and the primary site adds a new dimension to clinical trial conduct.

The Advantages of Satellite Sites for Oncology Trials

For people with cancer, satellite involvement can make clinical trial participation more appealing. Patients who seek inclusion in clinical research are likely to have a well-established relationship with their local oncologist, often preferring to stay with their doctor versus being transferred to a new oncologist at a larger research center further from their home. By virtue of their location, satellite sites enable clinical trial participants to stay within more familiar territory, eliminating the need to travel unnecessarily and lowering the barrier to entry for those who cannot accommodate the rigorous demands of study participation—often members of underprivileged groups, the exclusion of which results in skewed population metrics for trials.

Extracting the most benefit from the partnership between satellite and primary sites means sponsors must understand the varying degrees of maturity and centralization across the affiliate networks. These are just some of the considerations that can drive the selection of a satellite network partnership:

> **Capability:** Satellite sites come in all different shapes and sizes. It is crucial to match a study's protocol requirements with those of the AMC network and satellite sites being considered. Centralized training conducted by a primary academic site, along with oversight of start-up processes, is a common practice to ensure an on-time study start.

> **Capacity and Patient Match:** Satellite sites are likely to have less competition for certain patient groups than large cancer centers. Additionally, by bringing

trials out into more suburban areas, the enrollment area can expand to a broader and more diverse population.

Researching these criteria will be challenging for sponsors, but partnering with a qualified primary clinical trial site that has a well-established roster of satellite sites that may be relied on when the need arises eliminates hurdles regarding obtaining information on where suitable patients are located and where they are in their treatment journey.

Other Keys to Success with Satellite Sites

The primary academic site understands each of its satellite sites' capabilities and can identify those that make sense for a specific trial.

Some sites excel at investigational trial work, others at biospecimen collections. AMCs with satellite site networks ([Roswell Park](), for example) have intimate knowledge of their collective sites' strengths and patient populations. This enables sponsors to find the right investigators for their trial and generate higher quality data from the harmonized processes across this network.

Many organizations have invested heavily in SOPs, data platforms, and administrative services to create tremendous efficiencies and bring the capabilities of large sites to satellite locations. This helps them to:

- Ensure proper training, oversight, and infrastructure, potentially eliminating the need for site qualification visits at satellite sites.
- Provide contractual harmonization for most legal language and budgetary items—only small nuances reflect individual site capabilities and needs.
- Enable centralized, streamlined start-up activities, combined training activities, and potentially minimized delays in IRB approvals and navigation through other administrative red tape.

Many satellite site networks have uniform systems that centralize information on patient locations and diagnoses.

Targeting specific patient populations can be a daunting challenge. With standardized electronic medical record (EMR) systems, data collection can be streamlined to create more uniform treatment pathways and drive more consistent patient tracking and care.

Centralized and uniformed access to patient information simplifies the identification of potential trial participants and provides other value-added benefits to a study, including:

- SOPs and shared trial management platforms can drive consistency across a study to establish a strong baseline.
- Data from the EMR is uniform and always accessible, which eliminates the need to establish baseline using expensive claims data.

Satellite locations make a local presence possible, bringing science closer to patients.

Study participation will always pose some degree of burden, but with the COVID-19 pandemic, the paradigm shifted. The influx of patients to large academic sites made local community centers step up to handle the overflow of trial work. Despite this unplanned involvement, studies continued to run successfully, demonstrating the abilities of select sites to support oncology clinical trials and marking an important step forward toward more patient-friendly study practices.

Finding other ways to minimize the burden of participation on patients will be key to supporting them in their time of need, as well as for making studies more attractive—an important consideration for patient enrollment and an on-time study start. The challenges in this area include:

- The difficulties of travel—driving to metropolitan areas, parking, and time off work—make enrollment burdensome, discouraging people from participating in a trial. Having a trial accessible at a satellite location greatly reduce the hassle of commuting.
- Patient comfort is an important factor to reduce anxiety. This can include wanting to stay with their regular physician whom they trust (potentially avoiding loss of knowledge regarding the patient's condition).

- Improving representation is an ongoing challenge; however, suburban sites may be more accessible to certain groups who do not have the ability to take extended time off from work or the means to travel long distances.

The inclusion of satellite sites in a clinical trial can be a competitive differentiator for sponsors.

Growing competition and other enrollment challenges amplify the importance of easier trial participation experiences. Patient-centric considerations, together with network-enabled patient insights, make selecting satellite sites a far more digestible option.

By successfully pairing the right sites with the right studies, sponsors can improve the breadth and quality of data, drive enrollment more representative of real-world populations, and create better experiences by bringing the science closer to the patient. As the industry continues its shift toward decentralization, satellite sites will continue to play a key role in realization of patient-centric clinical trials.

As the numbers of trials continue to grow, sponsors who partner with academic sites with mature site networks to implement [decentralized clinical trial strategies](#) will benefit from the added capacity of highly skilled and motivated staff and faster enrollment from a broader patient reach, while continuing to maintain data quality. However, the most important driver of satellite site involvement lies beyond the dollars and cents.

Conclusion

Cancer can strike any person at any time and the impact spreads extends far beyond the patient, affecting families, caregivers, friends, neighbors, and coworkers. Today's reality is that many clinical trials are not accessible to the people who need them the most due to the high demands of study participation. This does not have to be the case. As various AMCs have already demonstrated, by implementing standardized processes and procedures, with centralized training and oversight by the primary site, they are able to bring the trials to the ones who matter the most—the patients.

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Esther Mahillo, PhD, MBA, is Vice President of Operational Strategy and Feasibility at Precision for Medicine in Madrid, Spain. She has more than 25 years of experience in the clinical research arena (22 of them in global oncology trials), and is a master's program professor at three different universities. In 2015, she was awarded the first prize of the Spanish Society of Medical Oncology contest for her work on the promotion of clinical research.

Technology Considerations When Onboarding and Offboarding Clinical Research Staff

Mollie Maggied, MSN, MHA, RN, AT-C, CPN; Paula Smailes, DNP, RN, CCRP

While technology is known to help with efficiency and productivity for clinical researchers, it can also be accused of leading to feelings of stress, burnout, and being generally overwhelmed.{1,2} Increased work volumes thanks to electronic workflows can be to blame, but staffing crises may also be at fault. Meanwhile, there exists a smaller number of experienced applicants being considered for open research positions across the drug and device research and development industry.{3,4}

That said, when the perfect applicant is hired, there may be a tendency to expedite onboarding. From the site perspective, there are obvious considerations with onboarding, such as adding new hires as staff on institutional review board (IRB)–approved research and providing training on the protection of human subjects.

Adding to that, the technology needs for today's clinical research staff are equally essential. When new hires onboard, access to technology becomes critical to perform daily workflows. Central to that are communication, such as e-mail, and data sharing (e.g., via electronic case report forms). While technology considerations are important to onboarding, they are crucial throughout the duration of employment to offboarding. Even internal transfers may have technology changes as they move from one position to another.

Onboarding

The Joint Task Force for Clinical Trial Competency (a collaborative effort of representatives from many organizations, including ACRP, managed by the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard) has identified data management and

informatics as key skills that clinical research staff should possess.{5} When applying this philosophy to new staff who are onboarding, access to technology should be one of the most important considerations. Given the needs and complications of standard operating procedures for using company e-mail and shared drives, electronic case report forms (eCRF), IRB portals, virtual meeting platforms like Microsoft Teams, Zoom, and WebEx, plus the electronic medical record (EMR) system, access becomes crucial to daily operations.

Consider the revenue cycle aspect of conducting research. Are billing systems available for sponsor or patient payments when access becomes critical? Is scheduling software ready for patient appointment–related tasks?

For some systems, such as those tied to eCRFs and EMRs, training also becomes a priority. Ideally, training will occur close to the beginning of the end-user's first official use of a system, so as to not leave him or her forgetting the system features that were taught. If the system is complex, use of a playground environment, if possible, can increase confidence until access to the live system becomes possible.

Meanwhile, since the onset of the pandemic, the use of telehealth has skyrocketed, including in clinical trial situations. Telehealth has become a much more widely used means to conduct clinical research visits and another system to which new hires require orientation.{6}

Consider the use of a checklist that includes both the technologies that the new hire needs oriented to, but also a competency checklist, to ensure that new hires have a basic understanding of both how to use the systems and how to apply any efficiency tools that may exist.

Offboarding

Why is this important if the research staff are transitioning into a new role in the organization or leaving it altogether? The answer lies with the consequences that may exist without a properly executed exit plan. There needs to be assurance that nothing is left undone, and while technology access has stopped, communication channels must continue. The following tasks, explained in more detail afterward, should be considered when an employee is leaving an organization or is an internal transfer leaving a research role:

- Remove research staff from being listed in research protocols when there are system impacts, from inclusion in organizational drives and e-mail systems, and from access to sponsor systems.
- If electronic documentation was used, ensure that any final research notes and encounters are signed.
- Place an "out of contact" message in e-mail and the EMR communication tools for staff who are leaving, along with guidance for whom should be contacted for future operations.
- Perform a messaging system "cleanup," including e-mail and EMR systems.

Removing Staff

If the EMR has research notifications based on protocols, there can be concern if staff members are not removed from studies upon leaving the organization or transitioning to new roles. If staff become internal transfers, alert notifications may continue to fire to them for patients on studies for which they are no longer covering. This could lead to Health Insurance Portability and Accountability Act (HIPAA) violations if study staff are no longer involved in patient care per protocol.

Staff who leave will need to have their replacements added as soon as possible to ensure communication continues for the study, regardless of technology medium. It is imperative these steps are taken to avoid issues.

Unfinished Notes and Encounters

Another possibility from research staff departure exists when notes are not signed by the research staff if the documentation method is electronic. This could result in incomplete notes being placed in a pending status that eliminates the possibility of other staff members being able to view unfinished work. Open notes could lead to open encounters in EMR systems, which could inevitably result in incomplete data for the research study. Given this consideration, protocol deviations or violations may be the ultimate negative outcome.

Messaging

Ongoing communication about coverage is important in that it allows people to know who is covering upon any departures of staff. Thinking of the multiple systems that clinical researchers

use, how many have a built-in messaging feature? For EMRs, an internal messaging system allow users to message other system users, keeping the dialogue secure within it. However, e-mail is just as important. Setting up an away message for the end-user who is leaving will allow others to contact the correct person if there are questions. It also ensures continuity of research-provided care. If the system allows, providing a start and end date can facilitate staff coverage. This process allows for a coworker to continually monitor incoming communication that are sent to the departing research staff.

Related to system messaging, it is important that the departing staff member have all messages acknowledged and reconciled. This ensures there are no outstanding issues requiring their attention. This also allows for the covering coworker to not be inundated with old messages that still may need attention after a staff mate's departure. Having the researcher clean up and handle messages and tasks within the system prior to his or her departure is in the best interest for all users of the system.

Conclusion

Technology has evolved into the backbone of clinical research operations. As we grow accustomed to electronic systems to execute daily workflows, how staff are properly oriented to systems will lead to faster functioning in their assigned roles. Offboarding is just as important to assure that there is no unfinished work and ensures a continuous flow of operations and smooth transitions when staff depart. If your organization has an informatics department, consider soliciting its help to facilitate and support staff during these times.

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Mollie Maggied, MSN, MHA, RN, AT-C, CPN, is a Clinical Informaticist for The Ohio State University Wexner Medical Center, specifically supporting oncology research.

Paula Smailes, DNP, RN, CCRP, is a Senior Systems Training and Optimization Analyst for The Ohio State University Wexner Medical Center and Principal Trainer for clinical research. She is also a Visiting Professor for Chamberlain College of Nursing and a member of the Content Advisory Committee of ACRP.

Article #1: **Building an Institutional Clinical Research Professionals Group at an Academic Institution: Evidence of Need and Initial Structure**

LEARNING OBJECTIVES
After reading this article, the participant should be able to summarize the structure, goals, and initial membership characteristics of the clinical research professionals group described herein, and to highlight key findings in the responses to the first annual membership survey.

DISCLOSURES
Demi Beckford, MHS; Kelly Boone, MA, CCRP; Jessica Fritter, MACPR, ACRP-CP; Grace Wentzel, CCRP, CHRC: *Nothing to disclose*

1. **What is the purpose of the Bloom initiative at Nationwide Children's Hospital?**
a. To encourage clinical research students from local universities to take on internships and job shadowing opportunities at the hospital.
b. To foster better relationships between the clinical research study staff and visiting sponsor representatives such as monitors and auditors.
c. To enable networking, collaboration, education and training, and mentoring among the institution's clinical research professionals.
d. To train all clinical research professionals at the institution to be part of patient recruitment and retention efforts going forward.

2. **What percentage of respondents to Bloom's first annual survey said they "Agree" that the initiative provides Networking opportunities?**
a. 17%
b. 22%
c. 37%
d. 50%

3. **Professionals from which job role were least represented in Bloom's baseline/interest survey?**
a. Research Assistants
b. Data Analysts/Managers
c. Investigators
d. Research Managers

4. **What was the prevalence of clinical research certification among respondents to the baseline/interest survey?**
a. More than 50% were certified and the remainder were not interested in becoming so.
b. Nearly 30% were certified, but only about 40% of the rest were interested in the idea.
c. Less than 20% were certified, but more than 80% were interested in working toward it.
d. Almost none were certified, but nearly all were willing to learn more about the topic.
[Test continues on next page…]

5.   Topics that respondents to the baseline/interest survey most wished to see covered in the Bloom initiative included which of the following?
a.   Networking, Development and Education, and Operations
b.   Study Finances, Recruitment and Retention, and Ethics
c.   Interviewing Skills, Study Binder Management, and SOP Development
d.   Regulatory Compliance, Quality Assurance, and Informed Consent

6.   What percentage of respondents to the first annual survey indicated that the group enhanced their professional development?
a.   28%
b.   37%
c.   39%
d.   61%

7.   Which of the following became opportunities for further networking through Bloom?
a.   Volunteer positions with the institution's job fairs
b.   Monthly online Happy Hours in different themes
c.   Quarterly People Like Me sub-group meetings
d.   Bowling and Bingo nights every other Thursday

8.   How did the pandemic affect the early activities of the Bloom group?
a.   Many meetings and events were canceled due to lack of PPE.
b.   The group disbanded and wasn't reformed until live events could be held.
c.   The institution's lawyers initially refused to allow the group to meet.
d.   In-person meetings and events were reformatted to virtual.

9.   New activities noted as being scheduled for Bloom in 2022 include which of the following?
a.   Clinical research speaker series
b.   Field trips to external institutions
c.   Poster presentations on study results
d.   Participation in local ACRP Chapter events

10.   Which of the following is noted as a limitation of the first annual member survey?
a.   Collection of the results took longer than anticipated due to the pandemic.
b.   Only a little more than one-quarter of the baseline survey respondents participated.
c.   Too many members had dropped out in the first year to achieve significance.
d.   Department heads discouraged staff from responding to the survey.

[Test continues on next page…]

Article #2: **Strategies for Selecting Appropriate Satellite Sites for Clinical Research**

LEARNING OBJECTIVES
After reading this article, the participant should be able to outline the characteristics of satellite sites as defined herein, describe the advantages of their uses by academic medical centers (AMCs), and provide examples of recommended practices for facilitating study operations between satellite sites and AMCs.

DISCLOSURE
Esther Mahillo, PhD, MBA: *Nothing to disclose*

11.   The author cites which of the following as an expected trend in clinical trial activities?
a.   Surges in availability with decreases in costs in the U.S., but declines in trials internationally.
b.   Heavy regulation of multisite trials will drive more of them out of the United States.
c.   U.S. expansion at a compound annual growth rate of nearly 6% over a seven-year period.
d.   More trials will focus on label expansions for existing drugs and far less on novel products.

12.   Which of the following is true of a "satellite site" as described in the article?
a.   An independent study site involved in academic medical center research on a case-by-case basis.
b.   A sponsor-owned study site located at a significant distance from the company headquarters.
c.   A member of a site management organization regularly involved in sponsored multisite studies.
d.   A physician-owned study site that only runs investigator-initiated trials on already-marketed products.

13.   Satellite sites are said by the author to have tremendous potential for added value to what kind of trials?
a.   Rare disease
b.   Pediatric
c.   First-in-human
d.   Oncology

14.   Which of the following tactics is noted as making it easier for satellite sites to participate in academic medical center–led studies?
a.   Access to details in the sponsor's investigator database.
b.   Acceptance of each site's own format for informed consent.
c.   Use of centralized institutional review board approvals.
d.   Funneling participant reimbursements through local banks.

15.   A satellite site's capability for on-time study start is noted as being aided by which of the following?
a.   Rerouting of excess participants at one site to another.
b.   Provision of centralized training by a primary academic site.
c.   Housing a sub-investigator onsite for the duration of start-up.
d.   Imposing significant financial penalties on sites for any delays.

[Test continues on next page…]

16.   Organizational investments geared toward creating efficiencies and bringing capabilities to satellite sites are noted as helping in which of the following areas?
a.   Enabling faster milestone payments from sponsors to investigators.
b.   Recruiting more diverse and compliant participants for studies.
c.   Harmonizing contracts for most budgetary items across the sites.
d.   Convincing more academic medical centers to conduct decentralized trials.

17.   Centralized patient information systems can help satellite sites in which of the following ways?
a.   By driving consistency in studies through SOPs and shared trial management platforms.
b.   By eliminating more would-be participants who are unlikely to be retained in the study.
c.   By reducing protocol amendments and the need to expand study cohorts in most cases.
d.   By shifting recruitment chores away from study coordinators and onto vendors.

18.   Having a trial accessible at a satellite location is noted as having which of the following benefits for participants?
a.   Increased likelihood of receiving active treatment.
b.   Reduced hassles of commuting to the study site.
c.   Quicker payment of stipends and receipt of gifts.
d.   Fewer inclusion/exclusion criteria for the study.

19.   Greater accessibility of suburban study sites to certain groups is noted as maybe resulting in which of the following benefits?
a.   Better opinions of clinical research among higher income participants.
b.   Lower levels of problems from "professional patient" participants.
c.   Wider interest about public participation in very long-term studies.
d.   Improved representation in the study of people who cannot travel far.

20.   With the rise of decentralized clinical studies, satellite sites are noted as playing a key role in realizing which of the following?
a.   Data transparency
b.   Real-world evidence
c.   Patient-centric trials
d.   Harmonized research ethics

[Test continues on next page…]

Article #3: Technology Considerations When Onboarding and Offboarding Clinical Research Staff

LEARNING OBJECTIVES
After reading this article, the participant should be able to summarize best technology-oriented practices for onboarding clinical research staff, provide examples of several key systems at sites in terms of training priorities and challenges, and highlight important actions to be taken during staff offboarding.

DISCLOSURE
Mollie Maggied, MSN, MHA, RN, AT-C, CPN; Paula Smailes, DNP, RN, CCRP: *Nothing to disclose*

21. The authors cite which of the following as critical for daily workflows when new hires are onboarded at study sites?
a. Conflict of interest
b. Protocol training
c. Sponsor oversight
d. Access to technology

22. The authors note which of the following as being identified by the Joint Task Force for Clinical Trial Competency as key skills that clinical research staff should possess?
a. Soft skills and time management
b. Diplomacy and proactiveness
c. Data management and informatics
d. Study start-up and close-out tactics

23. Access to company technology necessary for new staff in daily operations includes which of the following?
a. E-mail, EMR system, and virtual meeting platforms
b. Banking portals, ClinicalTrials.gov, and FDA hotlines
c. Investigator databases, monitoring reports, and wearables
d. ePROs, Good Clinical Practice, and AE alerts

24. What can be used to increase a new hire's confidence in using a complex system if live access to it is not immediately available?
a. PowerPoint presentations
b. Offsite training at the employee's expense
c. A playground environment
d. Virtual reality simulations

25. Systems-related checklists for orienting new hires should focus on which of the following?
a. Ergonomics and presentation skills
b. Competencies and technologies
c. Organizational finances and ethics
d. Compliance and oversight

[Test continues on next page…]

26.   Study site staff members who leave their organizations or transition to new roles should be removed from studies in which of the following?
a.   Electronic informed consent system
b.   Electronic patient-reported outcomes
c.   Electronic medical record system
d.   Electronic case report forms

27.   The authors cite open notes left by departing study staff in electronic medical records as potentially leading to which of the following?
a.   Incomplete data and protocol deviations
b.   GCP retrainings and coordinator departures
c.   Delays in study start-ups and patient recruitment
d.   IRB and data safety monitoring board sanctions

28.   Which of the following can help ensure continuity of research-provided care in cases of study staff departures?
a.   Ensuring that only a patient's primary care physician handles their study-related visit, procedures, and follow-up.
b.   Setting up an away message for the departing person's e-mails with new contact information for reaching out to the correct person.
c.   Sponsors mandating that study staff may not exit studies except at predetermined pause and review points.
d.   Principal investigators switching patients from active treatment to placebo when staff turnover becomes too challenging.

29.   The authors recommend that a departing study staff member do which of the following before leaving his or her position?
a.   Arrange to periodically return to their old site to handle unfinished tasks as needed.
b.   Personally train their replacement on all technology systems being used in ongoing studies.
c.   Make sure visiting monitors to their old site have their new employer's permission to contact them.
d.   Clean up and handle their outstanding messages and tasks in the EMR system.

30.   The authors recommend turning to which department for help with the flow of operations and transitions during staff offboarding situations?
a.   Regulatory Affairs
b.   Informatics
c.   Institutional Review Board
d.   Budget and Contracting